MAY 2 3 2014

510(k) SUMMARY

FMwand Handpiece SE

Date of Summary: March 18, 2014

General Provisions

510(k) Owner's Name:	Domain Surgical, Inc.
Address:	1370 South 2100 East Salt Lake City, Utah 84108
Contact Person:	Curtis Jensen, Vice President of Quality and Regulatory Affairs
Phone Number:	(801) 924-4958
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Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR §878.4400, Product Code GEI)
Proprietary Name:	FMwand Handpiece SE
Common Name:	Electrosurgical cutting and coagulation device and accessories

Name of Predicate Device(s)

- FMwand Ferromagnetic Surgical System, (Product Code GEI, HGI) 510(k) #K130606
- LiNA Medical SafeAir Smoke Pencil (Product Code GEI), 510(k) #K120454

Device Description

The FMwand Handpiece SE is a sterile, single-patient use, soft tissue cutting and coagulation device intended to be used with the FMwand Generator and FMwand Power Module (both previously cleared in 510(k) #K130606) and also with an effective user-supplied smoke evacuation system.

Technological Comparison

The FMwand Handpiece SE is identical in function to the FMwand Handpiece (K130606) with one exception: the FMwand Handpiece SE has an integrated smoke evacuation function which allows connection of the handpiece to a user-supplied smoke evacuation system. The FMwand Handpiece SE includes a removable shroud that fits on the handpiece tip to permit the device to remove the smoke from the surgical site as it is created. It is a single-patient use device intended to be provided to the user in a sterile state.

The FMwand Ferromagnetic Surgical System differs from the SafeAir Smoke Pencil because the SafeAir device is a standard monopolar electrosurgical device which uses a high density current through the inductance of soft tissue to create heat, and the FMwand Handpiece SE employs ferromagnetic induction to create the heat necessary to cut and coagulation soft tissue.

Device Comparison Table

Note: Shaded Items are identical.

Performance Feature	FMwand Handpiece SE	FMwand Ferromagnetic Surgical System Handpiece	LiNA Medical SafeAir Smoke Pencil
Manufacturer	Domain Surgical Inc.	Domain Surgical Inc.	LiNA Medical ApS
510(k) Number	To be assigned	K130606	K120454
Prescription/ OTC	Prescription Only	Prescription Only	Prescription Only
Product Code	GEI	GEI, HGI	GEI
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Basis Intended Use	Cutting and coagulation of soft tissue and removal of surgically generated smoke	Cutting and coagulation of soft tissue	Cutting and coagulation of soft tissue and removal of surgically generated smoke
Indications for Use	The FMwand Handpiece SE is indicated for cutting and coagulation of soft tissue during surgical procedures, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	The FMwand Ferromagnetic Surgical System is indicated for cutting and coagulation of soft tissue during surgical procedures, including Gynecologic procedures (open transabdominal only	The SafeAir Smoke Pencil is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system
Operation Function Switches	Two actuation buttons corresponding to dual user-selected high/low power levels.	Two actuation buttons corresponding to dual user-selected high/low power levels.	<CUT> button labelled yellow and proximal to electrode; <COAG> button labelled blue and distal to electrode
Power Supply	FMwand Generator (K130606) supplied by user	FMwand Generator (K130606) supplied by user	Monopolar generator supplied by user
Heat Generation Method	Ferromagnetic induction heating provides an elevated temperature blade which will cauterize tissue as it cuts	Ferromagnetic induction heating provides an elevated temperature blade which will cauterize tissue as it cuts	Application of a high-frequency current to soft tissue creates heat necessary to cut and/or cauterize.
Removable Suction Sleeve	Yes	No	Yes
Tip Lengths	75mm, 100mm, 125mm and 150mm	75mm, 100mm, 125mm and 150mm	Four different lengths available. Actual measurements unknown.
Complies with ISO 10993	Yes	Yes	Yes
Complies with IEC 60601-1	Yes	Yes	Yes
Complies with IEC 60601-2-2	Yes	Yes	Yes
Provided to the User in a Sterile State	Yes	Yes	Yes
Single-patient Use	Yes	Yes	Yes
Method of Sterilization	Ethylene Oxide – SAL 10^{-6}	Ethylene Oxide – SAL 10^{-6}	Ethylene Oxide – SAL 10^{-6}

Table 5-1: Device Comparison Table

Indications for Use

The FMwand Handpiece SE is indicated for cutting and coagulation of soft tissue during surgical procedures, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

Performance Testing Data Summary

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other similar devices on the market. The ability of the FMwand Handpiece SE to effectively remove smoke from the surgical site was shown through bench testing.

Safety and Biocompatibility Summary

The patient contacting materials used in the FMwand Handpiece SE were chosen for their biocompatibility, function and suitability for the intended use of this device. The materials and

colorants chosen are either in common use for medical devices or have been tested by accredited independent testing laboratories according to ISO 10993-1 and 510(k) Memorandum G95-1.

Conclusion

The FMwand Handpiece SE is substantially equivalent to the FMwand Ferromagnetic Surgical System Handpiece (K130606) with the addition of integrated smoke evacuation capabilities. The intended use of the FMwand Handpiece SE is the same as the FMwand Ferromagnetic Surgical System Handpiece with the addition of an indication for its smoke evacuation function. Both the FMwand Handpiece SE and the FMwand Ferromagnetic Surgical System Handpiece employ ferromagnetic induction to create the heat necessary to perform the electrosurgical function of cutting and coagulation of soft tissue.

The FMwand Handpiece SE differs from the SafeAir Smoke Pencil in the method used to cut and coagulate soft tissue. The SafeAir device is a monopolar electrosurgical pencil which uses a high density current through the inductance of soft tissue to create heat, and the FMwand Handpiece SE employs ferromagnetic induction to create the heat necessary to cut and coagulate soft tissue. Both the FMwand Handpiece SE and the SafeAir Smoke Pencil have similar smoke evacuation methods which include a vacuum orifice on the handpiece body and a removable suction sleeve which can be attached to the distal end of the handpiece. Both handpieces include a connection to a user-supplied smoke evacuation system.

The FMwand Handpiece SE has similarities and differences from both predicate devices; however the differences do not raise different types of questions of safety and effectiveness. The information presented in this premarket submission, including the bench testing, demonstrates that the FMwand Handpiece SE is as safe and effective as the predicate devices for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 23, 2014

Domain Surgical Incorporated
Mr. Curtis Jensen
Vice President, Quality and Regulatory Affairs
1370 South 2100 East
Salt Lake City, Utah 84108

Re: K140384
Trade/Device Name: FMwand Handpiece SE
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 18, 2014
Received: March 19, 2014

Dear Mr. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Submission: FMwand Handpiece SE

Indications for Use

510(k) Number (if known): K140384

Device Name: FMwand Handpiece SE

Indications for Use: The FMwand Handpiece SE is indicated for cutting and coagulation of soft tissue during surgical procedures, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

Prescription Use ____X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use: _____ (21 CFR 801 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S